Proposal 4: Use new labels to inform consumers about relative risk

Recommendation 4. Using its rulemaking powers, FDA should allow manufacturers to apply an accurate 'harm reduction' message to all non-combustible tobacco or nicotine products: "*This product presents substantially lower risks to health than cigarettes"* or other truthful, non-misleading communications.

Given there is 10-100 times difference in risk between cigarettes and non-combustible products (see section 1), how would consumers come to know this highly valuable health information? The statutory warnings that cover e-cigarettes, heated tobacco products and some novel products[1] and smokeless tobacco[2] are shown below.

E-cigarettes etc.	**WARNING: This product contains nicotine. Nicotine is an addictive chemical**
Smokeless tobacco	**WARNING**: This product can cause mouth cancer. **WARNING**: This product can cause gum disease and tooth loss. **WARNING**: This product is not a safe alternative to cigarettes. **WARNING**: Smokeless tobacco is addictive.

These warnings provide virtually no valuable, actionable or even truthful information to consumers.

- **Misleading about nicotine addiction**. Nicotine itself is not particularly dangerous to health. How addictive it is will depend on how rapidly and how high a peak exposure is reached in the brain as well as the interaction with other chemical agents in smoke – so addiction is strongly product and user-dependent. The term 'addictive' is vaguely understood and covers many forms of dependence – for example nicotine is not addictive in the same way as opioids even if it does meet almost all clinical definitions of an addictive substance for at least a portion of the population.
- **Misleading about health**. The evidence for smokeless tobacco causing mouth cancer, gum disease and tooth loss is very thin and may not apply to all forms of smokeless tobacco, for example snus[3] [4]. The specific health warnings do not convey the *magnitude* of these risks either by comparison to smoking or to other risks such as those arising from dietary choices.
- **Misleading about safety**. The most damaging warning claims smokeless tobacco is 'not a safe alternative to cigarettes'. Though technically true, this is profoundly misleading. It has been strongly criticized by experts for withholding the most crucial *differential* risk information[5].

A 2011 citizen petition filed on behalf of Reynolds American[6] urged the FDA to initiate administrative rulemaking to replace the safety warning with the following text (and a further variation on this):

> "*WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes"*

Though this contains truthful and non-misleading information, FDA determined it would not promote better understanding and rejected the petition in November 2015[7]. Despite this setback, the makers of these products do have a route by which they can make truthful health claims. This is the FDA's Modified Risk Tobacco Product application process (MRTP)[8], which is used to validate reduced-risk marketing claims. This process has been a total failure and, despite 33 applications, has yet to approve any modified risk claims[9], despite the huge variation in real-world risk. In June 2014, the snus company Swedish Match applied[10] to have the same warning as proposed by Reynolds applied to 8 of its own products. Despite a 130,000-page submission and more than two years of deliberation FDA announced

further prevarication on 14 December 2016[11]. This explanation for this decision[12] has revealed FDA's willingness to make up the rules as the process unfolds, and in doing so to create new barriers to candid communication of risks in a way that consumer groups argue works against the consumer interest[13]:

- FDA cherry-picked studies showing adverse effects rather than looking at the science overall[14].
- FDA insists that the company prove that its product *cannot* cause an adverse health effect before it can make a reduced risk claim.
- FDA insists that the company shows the product has lower risks for all possible health impacts, however trivial, not just the major causes of tobacco related disease

The FDA has a thoroughly flawed approach to risk communication:

- It relies on a tobacco company to find it commercially advantageous to apply in the first place. That is a bizarre and wholly inadequate basis for providing important risk information to the public.
- It relies on allowing tobacco companies to be the primary communicators of relative risk to the public, even though these companies are among the least trusted organizations in modern life.
- It applies only to that company's products, though near-identical products may be on the market and would be labelled differently.
- FDA does not have to justify its own warning regime or show it does not mislead consumers – the *status quo* is granted immunity from scrutiny or requirement to meet a public health benefit test.

Messages should *inform* consumers, not aim to manipulate their behavior to achieve some desired outcome. For example, if the undisclosed purpose of these warnings is to deter all nicotine use, they may perversely mislead citizens into continued smoking where they might have switched to smokeless tobacco to reduce risks.

References

1 FDA. "Covered" Tobacco Product and Roll-Your-Own/ Cigarette Tobacco Labeling and Warning Statement Requirements accessed 14 December 2016 [link]. This warning applies, *inter alia*, to vaporizers, e-cigarettes, and other electronic nicotine delivery systems (ENDS), dissolvables, gels and heated tobacco products.

2 FDA. Smokeless Tobacco Labeling and Warning Statement Requirements, accessed 14 December 2016 [link]

3 Lee PN. Summary of the epidemiological evidence relating snus to health. *Regul Toxicol Pharmacol*. 2011;59(2). [link]

4 Lee PN. Epidemiological evidence relating snus to health - an updated review based on recent publications. *Harm Reduct J*. England; 2013;10(1):36. [link]

5 Kozlowski LT, Sweanor DS. Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines. Int J Drug Policy. Elsevier [link]

6 FDA. Docket FDA-2011-P-0573, Initiate a Rulemaking Procedure to Adjust the Text of a Smokeless Tobacco ("ST") Product Warning Label Statement [link] Petition denied 11 May 2015.

7 FDA. FDA takes action on applications seeking to market modified risk tobacco products, 14 December 2016. [link]

8 FDA. Modified Risk Tobacco Products, accessed 14 December 2016 [link]

9 FDA. Modified Risk Tobacco Products - Summary of MRTP Application Actions. Accessed 4 January 2017 [link]

10 FDA. Swedish Match North America, Inc. MRTP Applications [link]. Swedish Match press release, 11 June 2014 [link]

11 FDA. FDA takes action on applications seeking to market modified risk tobacco products. 14 December 2016 [link]

12 FDA. Perspective: Lessons Learned from the First Review of MRTP Applications. 16 December 2016 [link]

13 CASAA. Swedish Match gets trapped in FDA's hall of mirrors. December 2016. [link]

14 Rodu B. FDA Rejects Plea to Correct Smokeless Tobacco Warnings; A Closer Look at Flawed Interpretations, Tobacco Truth. 21 December 2016. [link]